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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,104	09/27/2000	Alan P. Kozikowski	ZAA-012.01	6012

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FOLEY, HOAG & ELIOT, LLP
PATENT GROUP
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER	
FRIEND, TOMAS H F	
ART UNIT	PAPER NUMBER
1627	6

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
file copy	09/671,104	KOZIKOWSKI ET AL.	
	Examiner	Art Unit	
	Tomas Friend	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

Status of the Application

Receipt is acknowledged of an information disclosure statement on 06 August 2001 (Paper No. 5).

Status of the Claims

Claims 1-59 are pending in the present application and are subject to restriction and election of species requirements.

1-10, 27-36

Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1-10, 27-36

19

I. Claims 1-10 and 14-22, drawn to compositions of formula (I), classified in one of classes 530 and 534-552, and numerous subclass depending on the structure of R1.

II. Claims 11-18, drawn to a method for treating disorders caused by a deficiency in monoamine concentration in a human by administering a pharmaceutically effective dose of a compound of formula (I), classified in class 424 and/or 514, , and numerous subclass depending on the structure of R1.

III. Claims 23-26, drawn to a method comprising imaging the brain if a mammal by administering a radiolabeled compound comprising a radionuclide and a compound of formula (I), classified in class 424 and/or 514, , and numerous subclass depending on the structure of R1.

IV. Claims 27-36 and 45-48, drawn to compositions of formula (II), classified in one of classes 530 and 534-552, and numerous subclass depending on the structures of R1 and R2.

19-27 and 45-48.

V. Claims 37-44, drawn to a method for treating disorders caused by a deficiency in monoamine concentration in a human by administering a pharmaceutically effective dose of a compound of formula (II), classified in class 424 and/or 514, , and numerous subclass depending on the structures of R1 and R2.

VI. Claims 49-52, drawn to a method comprising imaging the brain if a mammal by administering a radiolabeled compound comprising a radionuclide and a compound of formula (II), classified in class 424 and/or 514, , and numerous subclass depending on the structures of R1 and R2.

VII. Claims 53 and 54, drawn to a method of inhibiting the reuptake of a monoamine transporter comprising contacting a monoamine transporter with a compound having the formula (I), classified in class 424 and/or 514, , and numerous subclass depending on the structure of R1.

VIII. Claims 55 and 56, drawn to a method of inhibiting the reuptake of a monoamine transporter comprising contacting a monoamine transporter with a compound having the formula (II), classified in class 424 and/or 514, , and numerous subclass depending on the structures of R1 and R2.

IX. Claim 57, drawn to a library of compounds having the formula (I), classified in class 435, and one of several digests, depending on the structure of R1.

X. Claim 58, drawn to a library of compounds having the formula (II), classified in class 435, and one of several digests, depending on the structures of R1 and R2.

XI. Claim 59, drawn to a method for detecting compounds capable of binding to monoamine transporters in inhibiting the uptake of monoamines, classified in class 435, digest 2.

The inventions are distinct, each from the other because:

2. Invention I and Inventions II, III, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the compositions of (products) of Invention I can be used in the methods of Inventions II, III, and VII.

A. Invention IV and Inventions V, VI, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of (products) of Invention II can be used in the methods of Inventions V, VI, and VIII.

B. Inventions I, II, IX, and X are different and patentably distinct compositions with different chemical constituents, different chemical structures, different chemical, physical, and pharmacological properties, and/or different reagents, starting materials, reaction conditions, and method steps, required for their making.

C. Inventions II, III, V-VIII, and XI are different and patentably distinct methods that require different compounds and method steps and produce different results.

D. Inventions IX and X and Inventions II, III, V-VIII, and XI are different and patentably distinct inventions. The methods of Inventions II, III, V-VIII, and XI do require the use of or produce the libraries of Inventions IX and X.

3. Because these inventions are distinct for the reasons given above and

a. have acquired a separate status in the art as shown by their different classification ;
b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
c. have divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

Election of Species

5. This application contains claims directed to the following patentably distinct species of the claimed inventions.

A. If applicant elects any of **Inventions I, III, or VII**, applicant is required under 35 U.S.C. 121 to elect a single disclosed **ultimate species of composition of formula (I)** (i.e. precise chemical structure including ultimate species and connectivities for R1-R14, A, and n) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

B. If applicant elects **Invention II**, applicant is required under 35 U.S.C. 121 to elect a single disclosed **ultimate species of composition of formula (I)** (i.e. precise chemical structure including ultimate species and connectivities for R1-R14, A, and n) AND a single disclosed **species of disorder** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

C. If applicant elects any of **Inventions IV, VI, or VIII**, applicant is required under 35 U.S.C. 121 to elect a single disclosed **ultimate species of composition of formula (II)** (i.e. precise chemical structure including ultimate species and connectivities for R1-R14) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

D. If applicant elects **Invention V**, applicant is required under 35 U.S.C. 121 to elect a single disclosed **ultimate species of composition of formula (I)** (i.e. precise chemical structure including ultimate species and connectivities for R1-R14, A, and n) AND a single disclosed **species of disorder** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

E. If applicant elects **Invention IX**, applicant is required under 35 U.S.C. 121 to elect a single disclosed **ultimate combination of species of R1,** a single disclosed **species of A,** AND a single disclosed **species of n** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

F. If applicant elects **Invention X**, applicant is required under 35 U.S.C. 121 to elect a single disclosed **ultimate species of R1** AND a single disclosed **ultimate species of R2** for

prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

G. If applicant elects **Invention XI**, applicant is required under 35 U.S.C. 121 to elect a single disclosed **ultimate combination of species of R1,** a single disclosed **species of A,** a single disclosed **species of n,** a single disclosed **ultimate species of R1** AND a single disclosed **ultimate species of R2** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. The species are distinct, each from the other, because they have different chemical structures with different chemical, physical, and pharmacological properties and require different starting materials, reagents, and reaction conditions for their making. The different disorders have different etiologies, causes, methods of treatment, and desired outcomes. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

J. Venkat
DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Tomas Friend, Ph.D.
22 February 2002

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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